Introduction

The eHealth Exchange Coordinating Committee (CC) has adopted the following eHealth Exchange testing policies to compliment and guide development of validation plans and test materials.

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1. Payload Conformance and Interoperability Testing

**Background:** During the trial implementations, a CCD / C32 data content specification was developed, tested and demonstrated to explore how a tightly constrained summary patient record could work in a network of networks environment. Shortly thereafter, based upon the capabilities available at the time, participants began exchanging data in production; however, an eHealth Exchange production specification was not formally adopted for the CCD or C32. Even so, it was generally understood by the Coordinating Committee and eHealth Exchange Participants that the CCD / C32 should conform to the corresponding HITSP construct and underlying standards. In addition, based upon experiences with the Trial Implementations, it was also assumed partner interfaces would be validated against the NIST CCD validator.

eHealth Exchange Participants already have an expectation of data content conformance for the CCD / C32 and have already been voluntarily testing conformance against the NIST validators. This approach is consistent with Stage 1 meaningful use and is essential to increased nationwide interoperability.

As Healtheway began development and launch of a new robust testing and certification program for the eHealth Exchange, renewed focus was placed on testing compliance and interoperability with a standardized content specification for the summary patient record that supported the following:

- Care coordination
- Transitions of care, in support of Stage 2 Meaningful Use requirements (MU2); and
- Authorized release of information for Social Security disability benefits determination

As part of Healtheway’s collaboration with the EHR | HIE Interoperability Workgroup (IWG), a multi-state initiative lead by the New York eHealth Collaborative (NYeC), a Joint Content Task Group was formed in the Fall of 2012. The objective of this group was to memorialize the summary patient record specifications already supported by most participants in production, as well as align these specifications with MU2. This Joint Content Task Group came to consensus on a standardized content specification that accomplished both objectives.

In light of this new specification, content policies for the eHealth Exchange need to be revisited to accommodate the following:

- Enable existing Participants to continue exchanging data in production without disruption;
- Standardize content shared across eHealth Exchange participants who share data for care coordination, transitions of care and Social Security purposes; and
- Assure alignment with MU2 rules.
1.1 General

- eHealth Exchange Participants shall attest to the content type they support in production, including the specific version.

1.2 eHealth Exchange Data Content Requirements and Conformance Expectations

eHealth Exchange participants who share data in support of care coordination, transitions of care and the SSA disability determination process shall, at a minimum, support one or more of the following documents and satisfy related testing:

i. **CCD, version 2.5 (Meaningful Use, Stage 1 Standard)**
   - Participant shall attest that participant has successfully pass conformance testing using the corresponding NIST validator tool, or that the participant uses a system which was certified for meaningful use, stage 1.

ii. **Enhanced C32 Summary Patient Record Content Specification (eHealth Exchange – EHR | HIE Interoperability Workgroup (IWG) Harmonized Content Specification, dated April 2013).**
   - Participant shall be required to test with the Exchange Testing Body, CCHIT, to demonstrate compliance with this specification.

iii. **Consolidated CDA (Meaningful Use, Stage 2 Standard)**
   - Participant shall attest that participant has successfully passed conformance testing using the corresponding NIST validator tool, or that the participant uses a system which was certified for meaningful use, stage 2.

Participants may share other types of documents via the eHealth Exchange such as:

- Other versions of the CCD through the eHealth Exchange. Validation of non-standard CCDs is not required. In this scenario, parties to the eHealth Exchange would have to address incompatibilities in exchange of non-standard data content.

- Unstructured documents, in accordance with available standards; however, testing of unstructured documents is not within the scope of the current eHealth Exchange testing program.
2. Testing Objectives

2.1: The eHealth Exchange testing process should focus only on validating that an entity has met the requirements for participation in the eHealth Exchange, in accordance with the eHealth Exchange specifications and validation plan.  

*For Example: Validating data content should only occur in accordance with a corresponding data content specification that has been adopted for use in Exchange.*

2.2: Other issues that arise should be escalated to the Coordinating Committee for consideration to assess whether advisory testing is warranted.  

EHealth resources should *not* be focused on testing operational-level, partner-specific issues.

*For example: While there are other areas where testing could be of value (e.g. testing behavior of patient correlations where systems have autonomy in deciding to correlate), these are out of scope and should not affect the validation outcomes for Exchange.*

3. Breaking Changes

**Background:** Testing often uncovers “breaking changes” that are identified while testing an applicant or participant. Issues uncovered real-time during the testing process should be handled as described in this policy.

*For example: While testing a candidate, the testing contractor finds an area of ambiguity in a specification. Upon clarifying it, it is discovered that many/all current EHealth participants would need to change in order to communicate with the candidate (in other words, the candidate is correct per the specification and all previous are not).*

3.1: Validation for the EHealth should be objective and repeatable, with consistent results based upon conformance with the specifications, validation plan and test cases in effect at the time an applicant / participant goes through validation. The validation process should not be subjective or discretionary to avoid introducing inconsistencies and potential for bias in the outcomes.

3.2: If errors are discovered due to ambiguity / errors in the specifications, then the issue should be addressed issue through the specification change management process. Applicants must conform to the specifications in effect at the time they test until specifications are corrected through the change management process.

3.3: If there is an error in the test scripts or test lab, but the entity is conforming to the specifications:

- The entity should be found conformant. An error in the lab or test cases should not prevent an applicant from proceeding through the testing process or going into production if the applicant conforms to the specifications.
o The validation process should not try to address known errors due to a bug in existing Participant systems or gateways. In this scenario, applicants should work with the other participants to address implementation-level issues. It is not desirable to have the EHealth testing process try to address partner-specific or gateway-specific issues since this is not the purpose of the EHealth testing process.

3.4: Partners need a mechanism (e.g. community of interest, wiki, etc) to collaborate and interact with other EHealth participants to identify and address partner-level or gateway-level issues, such as:

- Partner capabilities, including the purpose for which they wish to exchange
- Report or become aware of known issues with participants or systems/gateways, including versions affected. The task group recognizes that issues related to transport and content may need to be addressed differently.
- Provide a resource for implementers to learn about and address issues.

4. Validation Plan and Test Material Approval

4.1: The Validation Plan, including related test materials, which have an impact on a Participant’s involvement in Exchange, are be subject to the Performance and Service Specification Change Process (section 10.03) and required Coordinating Committee approval. This includes changes to the following:

- Validation plan
- Test cases

For Example:

- Changes in which tests are required for a given candidate (e.g. based upon functions supported)
- Make a critical fix to the validation plan / test cases identified during testing.
- Changes in content to the testing artifacts, such as:
  - Add coverage within a given feature (e.g. more testing of negative paths)
  - Changes to testing methods that also include substantive changes (e.g. Automate a previously manual test)
  - Update a test case
  - Add testing for a new feature (e.g. asynch, or Query for Docs (FindAssociations))
  - Add testing for a new spec
  - Add testing for a new version of a spec
  - Sunset testing for an old version of a spec
4.2: The following types of changes to validation materials should NOT be subject to the change management process in the DURSA.

- Changes to test data
- Fixes to testing tools or the test lab that do not otherwise change the testing requirements and expected outcomes. The testing team should further explore how NIST addresses changes with the automated testing tools used in the validation process.
- Editorial changes (e.g. to testing artifacts) should not be subject to the change management process.

5. Participant Retesting

**Background:** This policy aims to address when participants should be required to retest as a condition of continued participation in the eHealth Exchange. There are practical implications if existing participants are expected to retest as specifications and tests are modified. While retesting all changes may provide a higher degree of assurance for interoperability, this approach may not scale as eHealth Exchange participation grows. There are timing considerations with obtaining participant input regarding the changes, including notice when changes go into effect. In addition, there may be instances that could warrant shorter retesting timeframes (e.g. to implement and test an issue that fixes a security vulnerability).

5.1: Changes in specifications that also result in changes to the test materials or validation plan should be coordinated, reviewed and adopted by the change management process outlined in the DURSA. For example, changing specifications from “purpose of use” to “purpose for use”.

5.2: Changes to the testing artifacts only, that do not related to changes in specifications, can be reviewed on a case-by-case basis to determine whether retesting is necessary.

5.3: Any proposed requirements for retesting of existing participants should be identified and presented with the proposed testing changes to the CC. Retesting should be minimized to the extent possible without compromising trust and interoperability in the Exchange. Any proposed retesting should consider the following to provide the rationale for the retesting:

- The rationale (e.g. risk / benefit, criticality for trust and interoperability objectives for the Exchange, required to comply with applicable law, etc.)
- Cost and resource implications to participants and to the testing process.
- Scalability
- Other factors relevant to justifying the need for retesting

6. Scope of System Tested
**Background:** A consistent approach is needed in determining the scope of a system brought forward for EHealth testing. Various approaches were considered as this policy was developed – each with varying degrees of interoperability and burden. This policy aims to clarify how relevant system components are defined for testing, including expectations for retesting as those components change over time.

6.1 Applicants and EHealth Participants are expected to:

- Bring forth a production-ready system for validation.
- Identify the system components that are relevant to validation, including those components used to create or modify messages in accordance with the Performance and Service Specifications approved and in effect for the Exchange.
  - Message is intended to mean the transaction that is exchanged. This would not include the content in the absence of having approved content specifications adopted for the Exchange.
- Identify when to bring forward its system for retesting when it makes system changes that impact its compliance with the Performance and Service Specifications.

7. **Specification Versioning and Migration Approach**

**Background:** As participation in EHealth Exchange grows, there must be a consistent and methodical way to support versioning of EHealth Exchange specifications, while minimizing potential breakage of interoperability. Defining expectations and a systematic way to address version changes / updates will support expansion of connectivity across a rapidly growing community of exchange partners.

7.1 **General Policies**

7.1.1 There should be a multi-tiered approach for versioning and migration for the EHealth Exchange that aims to:

- Assure interoperability across use cases for both secure transport and core services;
- Allow communities to migrate timeframes that support varying development cycles; and
- Enable flexibility and variability where appropriate to support use cases implemented by various communities.

7.1.2 Specifications should be developed to maximize backward compatibility to the greatest extent possible. Changes that are not backward compatible should be made every few years to avoid breaking interoperability.
7.1.3 EHealth Exchange shall provide a period for dual use of old/new specifications, with a final cutoff date for all EHealth Exchange participants to migrate to a new version.

- A minimum of two versions of the specifications may be supported for a period of time. EHealth Exchange may adopt three or more versions of specifications as appropriate.
- EHealth Exchange shall identify an expiration date for the current version of the specifications.
- Additional version(s) may be adopted prior to the expiration date if needed.
- All participants would be expected to move to the revised version by that expiration date.

7.2 Single Version Adopted Across EHealth Exchange for Core Transport and Service Specifications

- There should be a common version of the secure transport and service specifications adopted for eHealth Exchange to enable interoperability across all use cases / profiles supported.
- There should be a period where existing and new versions are supported, with a final cutoff date by when all eHealth Exchange participants must migrate.
- Groups of eHealth Exchange partners, who share information for a particular use case, (i.e. eHealth Exchange profile) should be able to set their own migration timeframes within a targeted cut-off date.

  **Secure Transport – required for all use cases**
  - Authorization framework
  - Messaging platform

  **Services – at least one EHealth Exchange Pattern required**
  - Patient discovery / Query / Retrieve
  - Document submission
  - Publish / subscribe

- Version Frequency: Version updates should occur every couple years, with a period for dual use and a final cutoff date, comparable to the approach used for HIPAA Transaction and Code Set standards.

7.3 Optional Service-Related Specifications

- Two other specifications may be used by eHealth Exchange Participants, but are not required:
  - Web services registry
Access control policies

- These service-related specifications should not be anchored to any particular profile, but should be available for implementation across a myriad of use cases.
- These specifications should be versioned on a regular scheduled basis (e.g. annually), with a period for dual use and a final cutoff date.
- **Version Frequency**: Version updates should occur on a regular basis (e.g. annually), with a period for dual use and a final cutoff date, comparable to the approach used for HIPAA Transaction and Code Set standards.
- **Implementation Implications**: Participants who exchange for multiple use cases may need to support different versions for the same specification during the period of dual use.

7.4 Community-Specific eHealth Exchange Profiles and Data Content Requirements

**Background**: The eHealth Exchange has adopted a profile-based approach, which enables participants to determine which use cases and related specifications / content requirements they wish to support in production.

7.4.1 eHealth Exchange profiles define how a community of eHealth Exchange Participants wishes to exchange data using transport, service and content specifications to support their business needs.

7.4.2 Two profiles and their corresponding technical specifications are currently supported in production, including:

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| Query and Retrieve Documents for: care coordination, transitions of care / referrals or Social Security disability benefits determination | - Authorization framework  
- Messaging platform  
- Patient Discovery  
- Query for Documents  
- Retrieve Documents  
- One or more of the Summary Patient Record Document standards | - Web Services Registry  
- Access Consent Policies  
- Deferred Patient Discovery |
| Submit Documentation for CMS Programmatic | - Authorization framework | - Web Services Registry |
7.4.3 Profiles shall identify the business purpose and specifications required and specify how to constrain or implement those specifications as follows:

- **Secure transport** – must specify the current version in effect for EHealth Exchange and be updated to reflect new versions as described under 6.2 above.

- **Service specifications** – must specify at least one exchange pattern used and require the version in effect for Exchange. Must be updated to reflect new versions as described under 6.2 above.

- **Optional specifications** - identify whether optional specifications are used including version(s) supported. May be updated to reflect new versions adopted for Exchange.

- **Data content** – may define data content requirements, including version(s) supported. May be updated to reflect new versions adopted for Exchange.

- **Other requirements** – agreed upon by the community.

### 7.5 Migration Approach for Version Changes

**Background:** The first official production version of EHealth Exchange specifications was approved in 2010. During the early implementation of these specifications, additional changes were needed to address deficiencies, improve clarity and consistency in implementation. These changes (approved in 2011) were not backwards compatible and would require a migration from the 2010 to the 2011 specifications to assure interoperability among all EHealth Exchange participants. The following milestones were approved by the Coordinating Committee to support the migration, in conjunction with launching the new testing and certification program after September 2012. To assure continuity of operations and to facilitate expansion of the Exchange, there was a need and desire to move forward with supporting and testing 2011 specification implementations and to continue testing against the 2010 specifications beyond September 2012.
7.5.1 **Adopting eHealth Exchange Testing Requirements**

- The 2011 specifications release shall take effect on 3/1/2012, enabling any participant to voluntarily implement and use the 2011 specification release.
- A sunset date for the 2010 specifications release shall be defined by the Coordinating Committee. As of September 2012, such a sunset date has not yet been identified.
- The eHealth Exchange shall continue to support both the 2010 and 2011 specifications until participants have migrated to the 2011 version (targeted in early 2013).
- The new testing program being implemented to support the eHealth Exchange after September 2012 may continue testing against the 2010 specifications.
- Staff should work with participants to understand their timeframes for migration to the 2011 specifications, including the date in which they plan to discontinue supporting the 2010 version.

8 **eHealth Exchange Testing Strategy**

8.5 **Adopting eHealth Exchange Testing Requirements**

The Coordinating Committee shall:

- Adopt specifications and testing requirements, including a standardized configuration for the eHealth Exchange;

The Coordinating Committee may:

- Designate testing tools based upon a defined set of criteria for the eHealth Exchange.

8.6 **Designated eHealth Exchange Testing Tools**

Tools shall be updated in a timely manner as specifications and testing requirements change, and are capable of supporting multiple versions of a specification / testing requirement as adopted for the eHealth Exchange.

- Designate authorized testing entity(ies) to facilitate testing events and partner-level testing for Exchange; and
- Verify whether an entity has provided sufficient evidence of complying with eHealth Exchange requirements as a condition of participation.

8.7 **HIE Certified Network Systems**
8.7.1 Participants must use "HIE Certified Network" systems:

- The system may either be homegrown, open source or commercial products.
- The system must be a production-ready version that also reflects the standardized eHealth Exchange configuration.
- Other criteria may also be specified.

8.7.2 Participants should provide evidence that such systems:

- Conform to the eHealth Exchange specifications; and
- Have successfully tested and work with other systems through the eHealth Exchange participant testing program supported by Healtheway.

8.7.3 Systems shall be considered "HIE Certified Network" when:

- The system has successfully tested and determined compliant with the eHealth Exchange specifications, using test cases and tools adopted for the eHealth Exchange.
- The system has successfully met the HIE Certified Network criteria, completed testing and has been designated as being HIE Certified Network by a designated eHealth Exchange Testing Body.

8.8 Interoperability Expectations

8.8.1 Interoperability Definition:

- Participants can exchange, process and utilize the data for decision support purposes without subsequent testing or manual intervention for the declared profiles as it relates to transport, functionality (e.g. exchange modality) and payload (i.e. data content);
- Production systems securely interconnect, exchange messages, with both transport and functionality working; and
- Data recipients can consume payload and interpret the information as was intended by the submitting organization and use the information for decision support.

8.8.2 HIE Certified Network Systems Interoperate:

- Production ready systems developed by different technology solution providers interoperate (i.e. connect, communicate and exchange data in conformance with eHealth Exchange specifications, without error or further customization.)

8.8.3 eHealth Exchange Participants Interoperate in a Production Environment:
- eHealth Exchange Participants must use an HIE Certified Network system, once the HIE Certified Network program is launched and be interoperable for the profiles such Participant supports in production.

- eHealth Exchange Participants who use systems that were successfully validated prior to September 2012 through the ONC-supported testing and onboarding process (“Exempt Participants”) are not subject to this requirement. Exempt Participants shall, however, be required to use HIE Certified Network systems when the earlier of the following takes place:

8.9 Implementation-Level Interoperability Testing

- Participants should successfully test their implementation of an HIE Certified Network system – to demonstrate conformance and interoperability, for both transport and payload, with at least 2-3 other eHealth Exchange participants who use different HIE Certified Network systems.

8.10 Ongoing Compliance

- Participants are required to maintain compliance with the “Performance and Service Specifications” they plan to support in production as a condition of participating in eHealth Exchange.

8.11 eHealth Exchange Testing Body(ies) - ETB

- To the extent the Coordinating Committee designates eHealth Exchange Testing Body(ies):
  - Such a testing entity should be a not-for-profit organization that is both partner and vendor neutral (i.e., not hosted by a partner, even Federal, nor subcontracted to a vendor that may provide exchange systems).
  - The eHealth Exchange Testing Body shall foster a community mind-set while remaining independent.
  - The Coordinating Committee may designate more than one testing body.